



ASSOCIATION FOR MOLECULAR PATHOLOGY
Education. Innovation & Improved Patient Care. Advocacy.
9650 Rockville Pike, Bethesda, Maryland 20814
Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

August 10, 2017

Seema Verma, CMS Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Dear Ms. Verma:

On behalf of the Association of Molecular Pathology (AMP), thank you for this opportunity to submit written comments regarding new and reconsidered clinical diagnostic laboratory test codes for the Clinical Laboratory Fee Schedule (CLFS) for calendar year 2018 (CY2018). AMP is the leading international medical and professional association representing approximately 2,300 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics, and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry.

Below, we provide follow-up information to assist CMS in setting the CY2018 CLFS rates and provide recommendations on how new codes for CY2017 with no private payor data should be priced. At the meeting, AMP presented crosswalk recommendations for molecular pathology, genomic sequencing, and microbiology procedure CPT codes. We maintain that gapfill is not the appropriate pricing methodology for these codes as the CLFS is now populated with sufficient molecular pathology and genomic sequencing codes to serve as a viable basis for crosswalk recommendations. We thank both CMS and The Advisory Panel on Clinical Diagnostic Laboratory Tests (The Panel) for their engagement and input during this process. In general, AMP supports the Panel's votes for crosswalks for the codes on which we provided recommendation and continue to support for crosswalks for these codes.

Crosswalk Recommendation for Genomic Sequencing Procedure 814X5

The basis for our CY2018 crosswalk recommendations included analysis of the analytical method employed, overall resources utilized, types of genetic variants tested (*e.g.*, single nucleotide polymorphisms (SNPs), deletions, etc.), and the amount of genetic material interrogated. The Panel's voting for genomic sequencing procedure 814X5 (Hereditary peripheral neuropathies panel) resulted in no clear consensus, with 4 votes for AMP's recommendation of crosswalk to CPT code 81439 (Inherited cardiomyopathy) and 4 votes for gapfill. AMP reiterates its support for a crosswalk methodology for this hereditary GSP CPT code. AMP's crosswalk recommendation is based on the type and amount of genetic material tested as well as the analytical method

employed and overall resources utilized. Both codes are hereditary disease-based genomic sequencing procedures and both include sequencing of at least 5 genes. **Given the similarity in the relative resources required, we recommend that CMS adopt a straight crosswalk of 814X5 to existing CPT code 81439.**

Recommendations for Codes that Were New for CY2017 and No Private Payor Data

We appreciate CMS' willingness to engage and seek feedback from stakeholders during the initial PAMA pricing process. AMP urges CMS to continue to solicit provider feedback as the process continues, as well as early release of the preliminary CLFS rates for CY2018 in order to allow providers and provider organizations enough time to review and provide meaningful comment.

Upon review of the new CY2017 procedure codes listed as having no private payor data to price under PAMA, we identified the following codes as relevant to our membership: 81412, 81414, 81422, 81439 and 87483. AMP supports CMS' proposal to price these codes based on the same crosswalks adopted and finalized in 2016 using the CY2018 CLFS payment rates determined for the referenced codes. Please note that CY2017 CPT code 81439 (Inherited cardiomyopathy) is used as a crosswalk recommendation for CY2018 new code 814X5. We support a second degree crosswalk methodology for 814X5, meaning that 814X5 would be crosswalked to 81439 via its crosswalk to 81435.

Again, we thank you for the opportunity to submit recommendations to help CMS develop the CY2018 CLFS. We are happy to answer any questions about our recommendations and provide follow up information. Please direct your correspondence to Tara Burke, AMP Director of Public Policy and Advocacy, at tburke@amp.org.

Sincerely,

Samuel K. Caughron, MD
Chair, Economic Affairs Committee
Association for Molecular Pathology